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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,633	07/23/2003	George M. Hutchinson	066243-0166 (128639)	8071
7590	04/27/2009		EXAMINER	
JOSEPH D. KUBORN ANDRUS, SCEALES, STARKE & SAWALL 100 EAST WISCONSIN AVENUE SUITE 1100 MILWAUKEE, WI 53202			NAQI, SHARICK	
		ART UNIT	PAPER NUMBER	3769
		MAIL DATE	DELIVERY MODE	04/27/2009 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,633	HUTCHINSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHARICK NAQI	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 December 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-14,16,17,28,68,69 and 71-84 is/are pending in the application.  
 4a) Of the above claim(s) 13-14 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3,5-12,16,17,28,68,69 and 71-84 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .



## DETAILED ACTION

Examiner acknowledges the amendment filed December 15, 2008.

### ***Election/Restrictions***

Applicant's election without traverse of Species I drawn to claims 1-3, 5-12, 16, 17, 28, 68, 69 and 71-84 in the reply filed on December 15, 2008 is acknowledged.

Claims 13 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 15, 2008.

### ***Claim Objections***

Claims 13, 71 and 72 are objected to because of the following informalities:  
claim 13 has two periods at the end of the sentence, Examiner suggests that one of them be deleted;  
claim 71 has two periods at the end of the sentence, Examiner suggests that one of them be deleted;  
claim 72 has no period at the end of the sentence, Examiner suggests that a period be added.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5-12, 16-17, 28, 68-69, 71-75, and 81-84 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Independent claims 1 positively recites limitations that overlap statutory classes.

In this case, the applicant has positively recited **a method and an apparatus** in the same claim. More specifically, the limitations "a plurality of sensors generating a real-time physiological data stream" and "a controller receiving said real-time physiological data stream" (claim 1, lines 2 and 9) are method steps written in a system or apparatus type claim. See MPEP 2173.05(p) II. Dependent claims 2-3, 5-10, and 68 are rejected for being dependent on rejected claims.

In regards to claims 11-12, 16-17, 28, 69, 71-75 and 81-84 are drawn to a process. Under 35 U.S.C. §101 a process must 1) be tied to another statutory class (such as a particular apparatus) or 2) transform underlying subject matter (such as an article or materials) to a different state or thing. The claimed process steps do not transform underlying subject matter. Thus, to qualify as a 35 U.S.C. § 101 statutory process, the claims should positively recite the other statutory class (apparatus or thing) to which it is tied, for example by identifying the apparatus that accomplishes the method steps. Examiner notes that while some extra-solution activity is done with an apparatus in the form of sensors collecting the physiological data, this is an insignificant step and is not sufficient to pass the test.

[http://www.uspto.gov/web/offices/pac/dapp/olla/preognitice/section\\_101\\_05\\_15\\_2008.pdf](http://www.uspto.gov/web/offices/pac/dapp/olla/preognitice/section_101_05_15_2008.pdf)

[http://www.uspto.gov/web/offices/pac/dapp/olla/documents/bilski\\_guidance\\_memo.pdf](http://www.uspto.gov/web/offices/pac/dapp/olla/documents/bilski_guidance_memo.pdf)

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 74-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find support in the original disclosure for the following limitations “a geographically remote location” (claim 16, line 2) and “a geographically diffuse manner” (claim 74, lines 3 and 14).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 74-80 and 82-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 16, the limitation "a geographically remote location" in line 2 is indefinite because it is unclear from the claim language what exactly is considered geographically remote or from what original location/point is the claimed location geographically remote. Additionally, the specification does not provide any description or definition as to the scope of the phrase "geographically remote location".

Regarding claim 74, the limitation "a geographically diffuse manner" in lines 3 and 14 is indefinite because it is unclear from the claim language what exactly is meant by geographically diffuse or from what original location/point the claimed point is geographically diffuse. Additionally, the specification does not provide any description or definition as to the scope of the phrase "geographically diffuse".

Claim 75 is rejected based on its dependence on rejected claim 74.

Regarding claim 76, the limitation "a remote database" in lines 6, 8 and 10 is indefinite because it is unclear from the claim language from what original location/point is the claimed database remote.

Claim 77 is rejected based on its dependence on rejected claim 76 and additionally because it is unclear whether the "bill generator" claimed in line 4 is structure, or an algorithm or software. If the bill generator is an algorithm or software then the term/limitation will be given minimal patentable weight because it lacks structure that would be attributed to the apparatus claims.

Claims 78-80 are rejected based on their dependence on rejected claim 76.

In regards to claim 82, the limitation “remotely located database” in lines 2 and 4 is indefinite because it is unclear from the claim language from what original location/point is the claimed database remote.

In regards to claim 83, the limitation “receiving a clinician for a selection of the first rule set” in line 3 is indefinite because it is unclear how a clinician is received or what is meant by receiving a clinician for a selection.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 5-12, 16-17, 28, 68-69, and 71-84 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARICK NAQI whose telephone number is (571)272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./  
Examiner, Art Unit 3769

/Michael C. Astorino/  
Primary Examiner, Art Unit 3769

April 23, 2009